

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval
For
Other Than Full and Open Competition**

1. **Contracting Activity:** Department of Veterans Affairs Medical Center (VAMC), VISN 08, West Palm Beach, Florida
2. **Nature and/or Description of the Action Being Processed:** This is a request for other than full and open competition for a Brand Name Only procurement of three (3) Fresenius 2008T Hemodialysis machines.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The West Palm Beach VAMC currently has an established Fresenius Medical Information System (FMIS) in place. The FMIS communicates dialysis data from the Fresenius 2008T machine into the patient's records. The three Fresenius 2008T hemodialysis machine are being procured to work with the existing system. The estimated cost is \$49,500.00. VA2237 Number 548-14-2-440-0029 shall be used for this purchase.
4. **Statutory Authority Permitting Other than Full and Open Competition:**
☒ (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
☐ () (2) Unusual and Compelling Urgency per FAR 6.302-2;
☐ () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
☐ () (4) International Agreement per FAR 6.302-4
☐ () (5) Authorized or Required by Statute FAR 6.302-5;
☐ () (6) National Security per FAR 6.302-6;
☐ () (7) Public Interest per FAR 6.302-7;
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The VAMC requires three (3) additional Fresenius 2008T hemodialysis units. Fresenius 2008T is an FDA regulated medical device for which the manufacturer has proprietary rights to the hardware and software utilized in these hemodialysis machines. These 2008T hemodialysis units are the only units that interface with our existing FMIS system. These units are required so that patient treatment information can be transferred to VISTA CPRS to document treatment parameters for patients undergoing dialysis. The Fresenius 2008T hemodialysis units are essential to the Government's requirement, thereby precluding consideration of a product manufactured by another company.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** This requirement will be competed amongst several authorized distributors of the Fresenius 2008T unit. The Fresenius 2008T hemodialysis unit is a proprietary product of Fresenius Medical Care. VAMC currently has an established Fresenius Medical Information System (FMIS) in place which interfaces with the Fresenius 2008T units. Due to the proprietary nature of the software management system, no other units exist that interfaces with VAMC's FMIS.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The price is determined to be fair and reasonable based on the prices paid on previous purchases of Fresenius 2008T hemodialysis units.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research revealed that Fresenius 2008T hemodialysis is still the only unit that can interface with VAMC's FMIS. Prior to procuring additional units we will research the Market to determine if there are other products capable of fulfilling the agency needs without procuring a Brand Name Only item.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Fresenius Medical Care
11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before making subsequent acquisitions for the supplies or services required:** In the future, we will make attempts to purchases that don't limit competition.
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.



Michael Gardiner
Chief Biomedical Engineer
VAMC West Palm Beach

9/11/14
Date

13. **Approvals in accordance with FAR 6.304**

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Tammy Adams
Contracting Officer
NCO-8/SAO East Station 548

9/11/14
Date

- b. **PLS (Required \$3K up to \$150K):** I certify the justification meets requirements for other than full and open competition.



Christopher Murphy
Product Line Supervisor
NCO-8/SAO East Station 5480

9/11/2014
Date